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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,670	05/08/2001	Christoph Reinhard	PP-01699.002/200130.520	3261

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EXAMINER

SCHMIDT, MARY M

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 01/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/851,670

Applicant(s)

REINHARD ET AL.

Examiner

Mary Schmidt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 2-5 and 8-18, drawn to antisense compositions and methods of using antisense compositions in cells, including whole organisms, classifiable in classes 435, 536 or 514 subclasses 375, 24.5 or 44, respectively.
 - II. Claims 1, 6, 8-9, 13 and 15, drawn to ribozyme compositions and methods of using ribozymes in cells, including whole organisms, classifiable in classes 435, 536 or 514, subclasses 375, 23.2 or 44, respectively.
 - III. Claims 1, 8-9, 13 and 15, drawn to protein and polypeptide compositions and methods of using proteins/polypeptides in cells, including whole organisms, classifiable in classes 530 or 514, subclasses (300 or 350) or 2, respectively.
 - IV. Claims 1, 7-9, 13 and 15, drawn to antibody compositions and methods of using antibodies in cells, including whole organisms, classifiable in class 530, subclass 387.1.
 - V. Claims 1, 8-9, 13 and 15, drawn to small molecule compositions and methods of using small molecules in cells, including whole organisms, classifiable in classes 435 or 536, subclasses 375 or 1.11, respectively.

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2. Note that claims 1, 8-9, 13 and 15 are generic to all Groups I-V. Upon election of a Group, these elected claims will be examined on the merits for the elected genus (antisense, ribozyme, protein/polypeptide, antibody or small molecule) specified in that Group.

3. The inventions are distinct, each from the other because of the following reasons:

4. Inventions I, II, III, IV and V are unrelated from each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different chemical structures and different modes of operation based on their different chemical structures. Specifically, the invention of Group I is drawn to antisense compositions and their use. Antisense compositions are typically short nucleic acid oligonucleotides which operate by binding to a target gene followed by degradation by the enzyme RNase H. The invention of Group II is drawn to ribozyme compositions and their use. Ribozyme compositions are typically RNA compositions with specific structures such as binding arms and catalytic properties which allow the RNA to bind a target nucleic acid and cleave the target nucleic acid without the aid of an additional nuclease. The invention of Group III is drawn to protein or polypeptide compositions and their use. Protein and polypeptide compositions are comprised of amino acids which function therapeutically by interacting with other proteins such as receptors for instance, not via the nucleic acid interactions of antisense and ribozymes. The invention of Group IV is drawn to antibody compositions and their use. Antibodies are specific types of proteins which have immune function and bind specific epitopes or proteins depending on

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the target protein they were designed to bind. The invention of Group V is drawn to small molecule compositions and their use. Small molecule compositions are art recognized as organic molecules which are not nucleic acids or amino acids and have the capability to bind proteins such as receptors for instance. Due to the divergent structures and corresponding divergent modes of action of the compositions in each of the above designated Groups, the compositions are considered patentably distinct.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent classification and recognized divergent subject matter, and the search required for each of Group I, II, III, IV or V is not required for the other Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

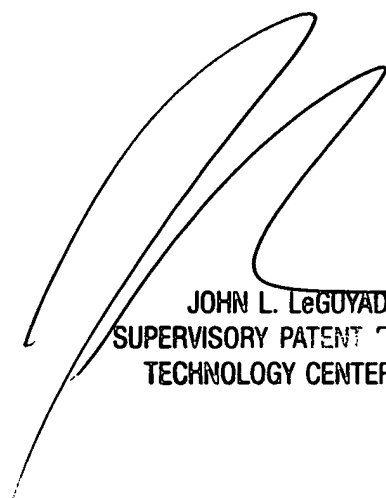
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.



JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

M. M. Schmidt
January 23, 2002